

OPP/AD/RMB1/SLAING/308-0152/MARCH 29, 2006

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bcc: FRANK SANDERS (7510C) BETTY SHACKLEFORD(7510C)
SUSAN LAING (7510C) DENNIS EDWARDS (7510C) MARSHALL SWINDELL (7510C)
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Mr. Brian K. Wehr
Corporate Counsel
Samsung Electronics America, Inc. "SEA"
105 Challenger Road
Ridgefield Park, NJ 07660

Dear Mr. Wehr:

Thank you for your letter of February 24, 2006, regarding SEA's recently introduced washing machine with SilverCare, a cold water sanitizing technology that relies upon silver and electrolysis to sanitize clothing.

In your letter you note that the washing machine is currently being marketed as a pesticide device consistent with guidance provided by Antimicrobials Division (AD) staff. We have recently re-evaluated the guidance provided by AD staff in the past with regard to the use of electrodes (silver, copper, zinc and others) and electrolysis and pesticide claims. In re-examining our past guidance, we reviewed the 1976 Devices Federal Register (FR) Notice (41 FR 51065) which consolidated and clarified the requirements at that time for devices. This FR notice also makes a clear distinction between the statutory definitions of "devices" and "pesticides."

"Thus, if an article uses physical or mechanical means to trap, destroy, repeal (sic) or mitigate any plant or animal life declared to be a pest at 40 CFR 162.14, it is considered to be a device. If the article incorporates a substance or mixture of substances intended to prevent, destroy, repeal (sic), or mitigate any pest, it is considered to be a pesticide."

Taking into account this clear distinction between the statutory definition of a device and a pesticide, we believe that our past guidance in this area was in error and has to be changed. We understand your position that the washer is being marketed as a pesticide device in compliance with FIFRA regulations on pesticidal devices. However, after carefully evaluating this situation, we believe that silver electrodes require registration under FIFRA as a pesticide, which is contrary to guidance we provided in September 2005. Silver is released into the laundry for the purpose of killing pests, which is a pesticidal claim.

Given the circumstances, we are prepared to work with you in preparing an application for registration for the silver electrodes. I suggest that a pre-registration meeting be arranged to discuss the information that needs to accompany your registration application. Note that since a "sanitization" claim is being made, efficacy data must be submitted since this is considered to be a public health claim.

Again, thank you for your letter. If your staff needs a contact person, they may reach Marshall Swindell, at 703-308-6341.

Sincerely,

Frank T. Sanders, Director
Antimicrobials Division

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